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7/9/98
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**MICHIGAN BREAST RECONSTRUCTION OUTCOME STUDY
YEAR FOUR, JULY 15, 1998**

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ABSTRACT

Initiated in September of 1994 and continuing through 1999, the Michigan Breast Reconstruction Outcome Study (MBROS) has brought together a consortium of 14 medical centers and 22 plastic surgeons to prospectively compare the long term outcomes of implant, pedicle TRAM and free TRAM breast reconstructions. Preliminary analyses of psychosocial, functional and patient satisfaction outcomes have been completed. Results of the psychosocial analysis of 99 patients suggest that there are measurable gains in psychosocial well-being following breast reconstruction. Compared with implant reconstruction, TRAM flaps may yield greater gains in body image, femininity, and sexuality. Although TRAM patients note increased abdominal pain, no detrimental effects on general health status, overall somatic pain, or physical functioning were identified. Preliminary analysis of the functional outcomes data of 71 patients suggest that, compared with implant techniques, both pedicle and free TRAM breast reconstructions may result in objectively measurable declines in abdominal wall function. However these functional changes are not reflected in patients' subjective assessments of their abilities to perform routine activities of daily living. Furthermore, as indicated by both isokinetic testing and questionnaire results, free TRAMs may not offer relative functional advantages over pedicle TRAMS. Finally, preliminary evaluations of patient satisfaction in 212 patients also are presented in this report.

INTRODUCTION

Background and Relevance

Each year in the United States, breast cancer strikes over 180,000 women. Although most of these patients are candidates for breast-conserving therapy (usually in the form of lumpectomy and postoperative radiation), many still undergo mastectomy. Loss of one or both breasts constitutes a major psychosocial stress for women already struggling to cope with a life-threatening illness. The disruptions in body image, interpersonal relationships, and other aspects of psychosocial functioning which result from mastectomy often have a significant negative effect on the recovering cancer patient's quality of life.

Previous research has clearly demonstrated the benefits of breast reconstruction for women undergoing mastectomy. Whether performed at the time of mastectomy or as a later secondary procedure, breast reconstruction may prevent or reverse many of the emotional and psychological disturbances seen in women undergoing mastectomy. Common sequelae such as impaired sense of well-being, compromised femininity, decreased feelings of sexual desirability can be reversed by the restoration of form and function.

Based on recent figures, there is a growing public acceptance of and demand for breast reconstruction. The American Society for Plastic and Reconstructive Surgeons estimates that 43,000 of these procedures were performed by its members during 1990. In 1990 (the most recent year for which data is available), expander-implant techniques constituted the majority of procedures for breast reconstruction. However, with the recent controversy over the safety and effectiveness of silicone gel breast implants, natural (autogenous) tissue techniques, most notably the transverse rectus abdominis musculocutaneous (TRAM) flap, have become increasingly common. Although they avoid the potential complications of prosthetic implants, TRAM flaps are more complex and expensive procedures. Given the growing prevalence of breast reconstruction in the United States, expander-implant and TRAM procedures are responsible for an annual outlay of health care dollars in the hundreds of millions.

Although considerable resources are currently being spent on breast reconstruction, relatively little information is available on comprehensive long-term outcomes of this treatment modality. There is a critical need for statistically credible research which reflects not just the technical feasibility and aesthetics of breast reconstruction, but which also shows the functional, psychological, and social benefits of such procedures. Finally, these demonstrated benefits of reconstruction must be assessed in relation to the costs of such operations. In essence, we must demonstrate the *value* of breast reconstruction.

Objectives

The objective of the Michigan Breast Reconstruction Outcome Study (MBROS) is to compare the long-term outcomes of the most common techniques of post-mastectomy breast reconstruction: tissue expansion/breast implant procedures, transverse rectus abdominis musculocutaneous (TRAM) flaps (free and pedicle), and latissimus dorsi flap/implant techniques. A four year prospective study, the project is adapting existing instruments and formulating new methodologies to assess outcomes in five categories: complication rates, aesthetic results, functional results, psychosocial status and costs. Study results will provide much needed information to patients, providers, and payers for determining the procedure of choice. In addition, the research will establish standardized methods for evaluation of breast reconstruction results in future studies. Finally, initial data assembled by this research can also be used for long-term analysis of breast reconstruction outcomes.

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Purpose/ Hypotheses

The purpose of the proposed research is two-fold: (I.) to develop a standard set of instruments for the evaluation of outcomes from breast reconstruction; and (II.) to use these instruments to compare outcomes for patients undergoing expander/implant reconstruction and those receiving TRAM reconstruction.

I. To achieve the first objective, multiple hypotheses will be tested:

- (1) Less costly clinical evaluations of functional outcomes have predictive validity (i.e., correlate highly with measures obtained from more costly isokinetic muscle testing).
- (2) Clinical evaluations of functional outcomes are reliable.
- (3) Less costly subjective assessments of both aesthetic and functional outcomes have predictive validity (i.e., correlate highly with more costly, objective measures).
- (4) Condition-specific, subjective assessments of functional and psychosocial outcomes have greater predictive validity than generic, subjective assessments.
- (5) Subjective assessments of aesthetic, functional, and psychosocial outcomes are reliable.

The results from testing the above hypotheses should identify the set of instruments which provide the most valid and reliable data at the lowest possible cost.

II. To achieve the second objective, multiple outcome measures of expander/implant and TRAM reconstructions will be assessed. The following null hypothesis will be tested for comparing outcomes from the two reconstruction procedures:

- (6) For expander/implant and TRAM procedures, there will be no differences in the five measured outcomes: (a) complication rates; (b) aesthetic results; (c) functional results; (d) psychosocial status; and (e) overall costs

Summary of Methods

Using patients recruited from the practices of 22 plastic surgeons and 13 medical centers in Michigan, Louisiana, Pennsylvania and Toronto, Ontario, Canada, the Michigan Breast Reconstruction Outcome Study (MBROS) is a prospective study comparing the outcomes of expander/implant, TRAM (free and pedicle) and lat dorsi reconstructions. As noted above, outcomes measured include complications, aesthetic results, functional results, psychosocial status, and costs. Patients are followed for two years; function and psychosocial status are assessed preoperatively, while all five outcome parameters are measured postoperatively at one year intervals. For patients enrolled less than two years from the end of the study period, follow-up will occur at one year post-surgery only.

The proposed research is a non-equivalent treatment group, multi-factor, full factorial design, with pre-test and post-test data collected prospectively. The two treatment groups are (1) patients undergoing breast reconstruction using tissue expansion/implants, and (2) patients undergoing reconstruction using TRAM flaps. Due to the use of latissimus dorsi/implant techniques in several of the participating centers, a small cohort of these patients has also been included for comparison.

As described in the body of our original proposal (pp 16-18), we determined that our sample size should be 462 patients with approximately 231 patients per procedure type. This sample size will minimize the possibility of either Type I errors (rejecting the tested hypothesis when it is true) or Type II errors (accepting the tested hypothesis when it is false).

The multi-factor aspect of the proposed research design, as well as the use of pre-test and post-test measures for several of the outcomes of interest, are intended to control for the differences in the patient populations between the two procedure groups. The factors to be included in the design, plus the number of levels of each, are described below:

- (1) Procedure type; two levels: (a) tissue expanders/implants and (b) TRAM flaps
- (2) Timing of procedure; two levels: (a) *immediate* (reconstruction at the time of mastectomy) and (b) *delayed* (reconstruction months or years following mastectomy)
- (3) Scope of procedure; two levels: (a) unilateral and (b) bilateral.
- (4) Surgeon; 22 levels (one for each surgeon who has agreed to participate).

The pre-treatment measurements of outcome variables are obtained prior to surgery. Post-treatment measurements will be collected at two different time points after surgery. This approach will identify the cumulative effect of some measures (e.g., complications and costs) and will help determine the earliest time point at which the other outcomes stabilize (e.g., functional and psychosocial status). Currently, the post-treatment data collection periods are at one year and two years following surgery. For patients enrolled less than two years prior to the end date of the study, follow-up measurements will be obtained at one year post-reconstruction only. Two of the outcome measures, complication rates and costs, are measured post-treatment only, as they are characteristics of the treatment itself, and therefore, have no pre-treatment measures.

As noted above, MBROS is studying five outcomes of breast reconstruction: complications, aesthetic results, functional results, psychosocial status, and costs. A variety of methods are being used to measure these parameters: in some cases, existing instruments are being employed in their original form, while in other instances, existing methodology is being modified to better assess the outcomes of interest. New techniques are also being tested for several of the five outcome parameters.

Postoperative complications are assessed with hospital chart and office record reviews at the conclusion of each patient's two year study participation. *Aesthetic results* are also being evaluated on the second anniversary following reconstruction using three different approaches: (1) computer analysis of digitized postoperative photographs; (2) physician ratings of post-operative photographs; and (3) patients' assessments of their own aesthetic results. Back, abdominal wall, and shoulder *function* are being examined preoperatively and at one and two year intervals after surgery with objective assessments (Cybex isokinetic testing). The effects of reconstruction on physical functioning are also assessed with activities of daily living (ADL) items on the study questionnaire administered at the same time intervals. To examine *psychosocial outcomes*, the preoperative and postoperative study questionnaires contain condition-specific questions as well as a battery of existing instruments including the SF-36, Basic Symptom Inventory (BSI), Modified Somatic Perception Questionnaire (MSPQ), and the Functional Assessment of Cancer Therapy-Breast (FACT-B). Finally, *costs of reconstruction* are being assessed at the conclusion of each patient's two year participation.

BODY

Project Status

MBROS was funded by the U.S. Army in July of 1994 for a four year period. After the hiring and training of project personnel, the study was initiated in late September, 1994. As described in the Statement of Work (SOW) included in the proposal, the goals for the fourth year of the project are listed below. Progress made during the past year towards completion of each milestone is also detailed.

MBROS Statement of Work (Months 37-49)

A. Status of Patient Recruitment:

In January, 1998, we received approval from the U.S. Army Medical Research Command to continue the study period for one additional year, until September, 1999. This has allowed us to continue patient recruitment during the fourth year of the study, and to follow patients recruited during year three for the full two year study period. The patients who have been recruited during the fourth year of the study will be followed for one year after surgery. During the first four years of the study, we have recruited 451 patients. Of these, 59 have been withdrawn from the study, leaving 392 participants. We are still recruiting for the study and expect to be very close to the sample size requirement of 462 patients noted in the body of our original proposal (pp 16-18).

Over the course of the study, we have taken a number of steps to improve the recruitment rate. To encourage and facilitate physician referral of patients, we began reimbursing staff costs for collaborating physicians at \$30.00 for each patient recruited. These funds are intended to help defray the costs of office personnel time, long distance telephone calls, etc. In addition, we have visited many of the physician's offices to encourage participation. We have also increased telephone and mail communication with the referring physician offices in a effort to remind them to refer patients to us for enrollment in the study.

We have also updated our enrollment criteria in order to include more patients in the study. In the past, we did not enroll patients who could not complete both the questionnaire and physical assessment portions of the study. This criterion caused us to eliminate many potential participants, particularly due to the physical assessment requirement. We encountered many patients who lived too far from one of our physical assessment sites or who, because of a very short time period between the enrollment date and surgery, were not able to fit in an appointment before surgery. Therefore, we have expanded our enrollment criteria to accommodate patients who can complete either the questionnaires or physical assessment exams only. We believe we can obtain valuable study data from these patients.

PATIENT ENROLLMENT BY MONTH: YEAR FOUR

July, 1997 (last 2 weeks)	1
August, 1997	9
September, 1997	4
October, 1997	7
November, 1997	4
December, 1997	5
January, 1998	11
February, 1998	5
March, 1998	6
April, 1998	7
May, 1998	2
June, 1998	3
July, 1998 (first 2 weeks)	6
Total	70

PATIENT ENROLLMENT BY PHYSICIAN: YEAR FOUR

PHYSICIAN	No. of Patients	No. Withdrawn	No. of TRAMS	No. of Implants	No. of Lat Dorsi	HOSPITAL
Wilkins, Edwin	19	2	12	6		Univ of Mich.
Cederna, Paul	4		2	2		Univ of Mich
Shaheen, Ken	3			3		Beaumont
Izenberg, Paul	2		2			St. Josephs
Houin, Herman	2		2			Henry Ford
Beil, Richard	2		1	1		St. Joseph's
Hammond, Dennis						St. Mary's
Schenden, Michael						Beaumont
Bengston, Bradley						Holland Comm
Drever, Michael	2		2			Toronto General
Darian, Vigan						Henry Ford
Nelligan, Peter	2	1	1			Toronto General
Smith, David						Univ of Mich.
Mizgala, Cynthia	12	1	8	3		Ochsner Med. Ctr.
Sherbert, Dan						Sinai Hosp.
Ringler, Steve						Holland Comm
Semple, John	13	1	11			Women's College
Ganos, Doreen						Henry Ford
Brundage, Scott						Butterworth
Ladin, Daniel	1		1			Henry Ford
Banducci, Dennis	4		1	2		Hershey Med. Ctr.
Colony, Lee						Mich. State
Kuzon, William						Univ of Mich
Mucci, Samuel	4		1	3		Beaumont
Oneal, Robert						St. Joseph's
Total	70	5	45	20		

B. Status of Patient Enrollment

As we have continued following patients for the two year study period, we have encountered a number of issues related to attrition. Some patient attrition is unavoidable because of complications, disease progression or death. However, we have also encountered a few patients who just did not wish to continue. In order to keep our patients interested in the study during the long enrollment period, we developed a patient newsletter, the *MBROS Update*. (attachment B) Response has been positive and we hope that the newsletter communicates to patients that they are part of an important research study, and also keeps them up to date on issues and studies related to breast cancer and reconstruction.

MBROS Patient Status

As noted in our report last year, we expanded the status categories for patients enrolled in the study. Previously, the patient status was either active or withdrawn. As we have enrolled more patients, and been confronted with many variations of patient participation, we have expanded these categories as follows:

A = Active
P = Partial (Patient is active but will not be completing all of the study requirements.)
L = Limited (Patients are not active in the study, chart reviews will be completed only)
W = Withdrawn (Patients completely withdrawn from the study)
C = Complete (Patient has completed all study requirements)
I = Incomplete (Patient has reached the end of study period but is missing some study data that cannot be obtained)

Definitions:

Active Patients - These are patients we enroll for whom we expect to receive all three questionnaires and all three physical assessment reports.

Partial Patient - These are patients we enroll for whom we know in advance that they will be missing part of the study requirements. In most instances, this will be the physical assessment data.

Limited Patient - These are patients who will have a limited role in the study. They were unable to continue active participation due to a change in surgical procedure, recurrence of cancer, or death. They will not be contacted by us to complete further study requirements, but chart reviews will be completed in order for us to assess complications, and all completed data will be used for analysis purposes.

Complete Patients - These are patients who have fulfilled all of the study requirements - three questionnaires and three physical assessments.

Incomplete Patients - These are patients who have come to the end of the two year study period, but some data is missing which cannot be obtained. This could be because the patient was enrolled as a partial patient in the beginning or it could be an active patient who was unable, due to medical complications, or unwilling to complete all of the study requirements. Data from these patients will be used for analysis.

Withdrawn Patients - Patients who have been withdrawn from the study. These patients did not provide any useful data for analysis.

STATUS OF ALL PATIENTS ENROLLED

Status	#	All Ques. Complete	Pre & 1st post-op Quest. Complete	All Physical Assessmts. Complete	Pre and 1st yr post-op assesmts.. Complete
Active Patients	205		91		91
Partial Patients	26		9		1
Completed Patients	105	105		105	
Incomplete Patients	32	18	12	3	16
Limited Patients	24		7		3
Withdrawn Patients	59	---	---	---	---
Total	451	123	119	108	111

REASON FOR LIMITED STATUS:

# of Patients	Reason for Limited Status
1	1- Patient did not complete the pre-operative questionnaire and/or functional assessment prior to surgery.
0	2-Patient was unable to physically complete the functional assessment because of co-morbid problems.
2	3-Patient changed her mind about wanting to participate
0	4-Surgery was canceled
10	5-Patient's surgical treatment option changed during the study due to complications (i.e. began as an expander/implant, changed to TRAM or the reverse (Chart Reviews will be done on all of these patients)
5	6-Patient developed a recurrence of cancer and was too sick to continue
6	7-Patient died
0	8-Other

REASON FOR WITHDRAWN STATUS:

# of Patients	Reason for Withdrawn Status
20	1- Patient did not complete the pre-operative questionnaire and/or functional assessment prior to surgery.
5	2-Patient was unable to physically complete the functional assessment because of co-morbid problems.
7	3-Patient changed her mind about wanting to participate
18	4-Surgery was canceled
2	5-Patient's surgical treatment option changed during the study due to complications (i.e. began as an expander/implant, changed to TRAM or the reverse (Chart Reviews will be done on all of these patients)
1	6-Patient developed a recurrence of cancer and was too sick to continue
1	7-Patient died
5	8-Other

C. Administer preoperative functional tests and questionnaires to new study patients, and postoperative functional tests and questionnaires to study patients.

Pre-operative functional tests and questionnaires have been administered to all active patients. One-hundred and five patients have completed all study requirements. An additional 32 patients have come to the end of the study period and, while they have not completed all study requirements, they have provided us with significant usable data. Of these 32 partially complete patients, 18 have completed all three questionnaires, 12 have completed the pre-operative and first-year post-operative questionnaires, three have completed all three physical assessments, and 16 have completed the pre-operative and first year post-operative physical assessments.

As noted in the table on the previous page, there are 200 active patients. Of these 200 patients, 109 have completed the pre-operative questionnaire and physical assessment. Ninety-one patients have completed both the pre-operative and first year post-operative questionnaires and physical assessments.

Copies of the preoperative and postoperative patient questionnaires are included in Attachment A.

D. Continue acquisition of clinical data from participating hospitals and surgeons.

Chart reviews have been completed on 151 patients who have come to the end of the two year study period. This summer, we are continuing to complete chart reviews for patients from all study hospitals in the state of Michigan. Several of the hospitals in the study are a considerable distance from Ann Arbor. Since travel to these hospitals will require significant expenditures for air fare and lodging, chart reviews will be completed at the end of the study period when all patients from those facilities can be done at one time. Also, in the collaborating physicians' offices, a complication check-list has been attached to each study patient chart. These check-lists will be returned to the UM Outcomes Office following the end of the two year period and will serve as an additional mechanism for collecting complication data and for verifying hospital record information on adverse post-operative events.

E. Continue collection of cost data from participating hospitals and surgeons.

The comparison of costs between the TRAM and implant methods of reconstruction is one of the five categories in which patient outcomes will be studied. The total cost of treatment for each study patient will consist of all professional and hospital costs associated with the patient's hospitalization for the reconstruction, plus the costs of any subsequent care received (inpatient or outpatient) that is related to the reconstruction.

As mentioned in last year's report, we are collecting billing data from our participating sites, including services provided and corresponding charges. Our plan last year was to assign University of Michigan Relative Value Units (RVUs) to services provided, in an effort to apply a standard method of cost measurement across all participating sites. In addition, we were working on identifying an appropriate conversion factor for translating professional charges to RVUs. (UM RVUs have only been developed for hospital services, not for professional services.)

We have collected billing data for 238 primary procedures and 176 secondary procedures, and continue to collect these data as our patients complete their treatment. These data generally include a detailed list of services provided, the individual charges associated with each service, and total charges. After reviewing these data, we realized that it would be virtually impossible to assign UM RVUs to each and every line item on the bills. Therefore, we have decided to limit our RVU assignments to those items that are likely to account for the majority of patient costs and the majority of variability in patient costs: inpatient daily room costs, operating room time, recovery room time, and non-professional anesthesia time (i.e., CRNAs). These are services we can identify from each hospital's bills *and* assign UM RVUs. The following table illustrates this financial analysis.

MBROS Financial Analysis To-Date

Patients are 1-2 years post-surgery. All primary and secondary procedures included, excluding tattooing.

Immediate Reconstruction Patients

Group	n	Average Resource Use			
		OR Hours	Inpt Days	UM RVUs ¹	Charges ²
Bilateral implant	11	10.1	5.3	3832	24,691
Bilateral Free TRAM	6	15.4	7.2	4872	32,315
Bilateral Pedicle TRAM	7	10.4	8.1	4295	25,552
Unilateral implant	27	6.4	4.7	3021	17,098
Unilateral Free TRAM	28	11.9	6.8	4196	24,667
Unilat Pedicle TRAM	34	8.8	5.5	3337	18,749

Group	n	Ratios of Resources Used ³			
		OR Hours	Inpt Days	UM RVUs	Charges
Bilateral implant	11	1.6	1.1	1.3	1.4
Bilateral Free TRAM	6	2.4	1.5	1.6	1.9
Bilateral Pedicle TRAM	7	1.6	1.7	1.4	1.5
Unilateral implant	27	1.0	1.0	1.0	1.0
Unilateral Free TRAM	28	1.9	1.4	1.4	1.4
Unilat Pedicle TRAM	34	1.4	1.2	1.1	1.1

Delayed Reconstruction Patients

Group	n	Average Resource Use			
		OR Hours	Inpt Days	UM RVUs ¹	Charges ²
Bilateral implant	1	11.5	7.0	5186	32,300
Bilateral Free TRAM	2	14.5	7.0	4568	26,155
Bilateral Pedicle TRAM	1	13.0	8.0	5047	34,280
Unilateral implant	6	5.1	1.3	1893	12,312
Unilateral Free TRAM	8	12.2	7.5	4392	26,226
Unilat Pedicle TRAM	18	8.2	5.2	2973	16,510

Group	n	Ratios of Resources Used ³			
		OR Hours	Inpt Days	UM RVUs	Charges
Bilateral implant	1	2.3	5.4	2.7	2.6
Bilateral Free TRAM	2	2.8	5.4	2.4	2.1
Bilateral Pedicle TRAM	1	2.5	6.2	2.7	2.8
Unilateral implant	6	1.0	1.0	1.0	1.0
Unilateral Free TRAM	8	2.4	5.8	2.3	2.1
Unilat Pedicle TRAM	18	1.6	4.0	1.6	1.3

¹UM RVUs include OR hours, recovery room hours, and length of stay.

²Charges include everything (total hospital bill) except professional services.

³Ratio data: Unilateral implant is set at 1.0; resource use for other procedures is measured relative to this amount.

Regarding our effort to identify an appropriate conversion factor for translating professional charges into RVUs, we have decided to use Medicare RBRVS (Resource Based Relative Value Scale) costs for professional services for 1992, the same year in which the UM RVUs were developed.

In addition to assigning UM RVUs to hospital services, we will perform three additional financial analyses. The objectives of the additional analyses are to: (1) ensure widespread acceptability of our analyses (not everyone will necessarily accept RVUs developed by the University of Michigan as an accurate measure of resource utilization); (2) allow the analysis of professional and hospital costs *combined*, which is difficult using the UM RVU system; and (3) conduct a sensitivity analysis of alternative measures of costs, which may be useful to other researchers. The three additional analyses are described below:

Reimbursement rates: One of the major objectives of this research is to provide information to payers that will help determine which treatments should be reimbursed. To this end, financial data on relative reimbursement rates of alternative procedures are as useful as cost data. Therefore, we are obtaining data on expected or actual reimbursement rates from the participating hospitals and physicians.

Actual charges: It is generally recognized that charges are a very poor measure of costs, because of the lack of standardization across hospitals in the relationship of costs to charges. Nevertheless, charge data are the easiest and most comprehensive financial data to obtain from hospitals and physicians; and although the absolute charges are not likely to have much relationship to actual costs, it is possible that the ratio of charges among the procedures of interest may be similar to the ratio of costs. Therefore, we plan to analyze charge data for all study patients. We will compare the ratio of charges for the different procedures to the ratio of reimbursement rates and ratio of RVUs, to see if the results are similar.

Resource utilization: Because clinicians, payers, administrators, and other researchers may find fault with one or more of our assumptions in our analyses of RVU, reimbursement, and charge data, we are also collecting data on the major resources used in breast reconstruction treatment: length of inpatient stay, operating room time, and recovery room time. Some of our participating hospitals provide these data on the bills we are obtaining; for other hospitals we are collecting these data as part of our chart reviews. Thus far we have collected resource data on 152 patients. After we analyze the data and present descriptive results for each of the different procedures, other facilities or payers can calculate their own costs by multiplying each unit of resource use by the unit cost figure of their choice.

F. Conduct aesthetic evaluations (surgeon evaluator ratings, patient ratings, and anthropometric assessments) of patients enrolled in months 1-12.

At the end of the two year study period, we request that the referring physician take a set of photos of the study participants. As patients are completing the study period, we have begun to receive these photos. To date we have received photos on 54 patients. Each photo has been converted to a digital image using a computer equipped with a Nikon Coolscan transparency scanner. Image analysis software is used to compute breast symmetry indices for each patient. Analysis of the breast symmetry will allow for objective comparison of reconstructive results obtained with different surgical techniques.

Surgeon evaluator ratings will be completed at the end of the study. At that time, the postoperative photographs will be submitted to a panel consisting of three UM staff plastic surgeons who have not been involved with the care of any MBROS patients. Overall aesthetic outcomes will be rated

by each evaluator using a modification of the Garbay, et al. rating system which is a composite of five subscales including breast volume, contour, mound placement, scar, and inframammary fold.

Patients' subjective assessments are measured by their responses to a set of questions regarding their satisfaction with the aesthetic results of breast reconstruction. These questions are included in the post-surgery evaluation form.

RESULTS

PSYCHOSOCIAL OUTCOMES

Preliminary analysis was completed on ninety-nine consecutive MBROS patients undergoing postmastectomy breast reconstruction. As noted in the body of this report, women selecting tissue expander/implant or TRAM flap (pedicle or free) breast reconstruction were included. Participants were administered the pre-operative and first year post-operative questionnaires. The pre-operative and post-operative questionnaires include the Medical Outcome Study Short Form (MOS-SF 36), the Functional Assessment of Cancer Therapy (Fact-B), and additional condition-specific questions which were utilized to address body image and pain. Gain scores (difference between pre-and one year postoperative scores) were calculated for each patient's questionnaire subscales and condition-specific items. Analysis of covariance (ANCOVA) was used to determine the effect of procedure type and timing on changes in physical, psychological, social, and role function, controlling for baseline score. Paired T-tests were used to determine if overall gain scores for patients undergoing all types of breast reconstruction were significantly different over time.

Of the 99 patients analyzed, 74 elected TRAM flap reconstruction (38 free and 36 pedicle TRAM flaps) and 25 patients underwent implant reconstruction. Immediate and delayed reconstructions were performed in 68 and 31 patients, respectively. The mean age was 48.8 years. There were no statistically significant differences in age, race, employment status, or educational level between the groups.

Our analysis revealed statistically significant gains in psychosocial well-being in all patients one year following breast reconstruction, as compared to their pre-operative status. Specifically, patients undergoing all types of reconstruction reported improved physical, social, and emotional functioning, general mental health, and vitality ($p<0.004$).

Statistically significant psychosocial improvements were identified in patients undergoing both immediate and delayed breast reconstructions. Although the delayed breast reconstruction patients reported a significantly better emotional status preoperatively ($p<0.0001$), all patients experience significant improvements in emotional status one year postoperatively ($p<0.001$), as compared to their preoperative status. Patients undergoing delayed reconstructions noted significantly greater gain scores for perception of general health ($p=0.031$), clothing fit ($p=0.001$), "feelings of being whole" ($p=0.001$), and femininity ($p=0.001$) as compared to immediate reconstruction patients.

Multiple statistically significant differences were identified between TRAM flap and implant reconstruction patients. TRAM patients reported increased femininity, improved body image, increased satisfaction with clothing fit, and overall "feelings of being whole" and "attractive" as compared to implant patients ($p<0.001$). TRAM patients also noted increased gain scores for sexual attractiveness ($p=0.0001$). The condition specific items identified higher gain scores for abdominal pain and tightness ($p<0.001$) in TRAM patients, as compared to implant patients, but a lower gain score for breast pain ($p=0.007$). Despite these findings, there were no statistically significant differences in general health, physical functioning, or overall somatic pain based on reconstruction type, one year postoperatively, as compared to pre-operative status.

There were no significant differences in breast pain, abdominal pain/tightness, overall somatic pain, general health, or physical functioning between patient undergoing free or pedicle TRAM flap reconstruction.

In conclusion, this prospective analysis suggests that there are measurable gains in psychosocial well being one year following TRAM flap and implant breast reconstruction. TRAM flap reconstruction may yield improved body image, femininity, sexuality, and overall feelings of being whole, when compared to implant reconstruction. Although TRAM patients note increased

abdominal pain and tightness, no detrimental effects on general health status, overall somatic pain, or physical functioning were identified. There are no significant differences in psychosocial outcomes between free and pedicle TRAM reconstruction. Patients undergoing immediate and delayed breast reconstruction experience similar improvements in emotional status, body image, and "feelings of being whole" one year postoperatively, adjusting for baseline variances.

FUNCTIONAL OUTCOMES

Preliminary analysis of functional data was completed for the first 71 consecutive MBROS patients undergoing immediate or delayed, unilateral breast reconstruction following mastectomy. Within the study group, sixteen women had expander/implant reconstruction, 26 had pedicle TRAM flaps and 29 had free TRAM reconstructions. Our analysis sought to compare the functional results of these three types of reconstruction to address two issues: (1) Do these procedures result in objectively measurable changes in muscle function? (2) If objective changes in function are observed, are these changes reflected in the patients' assessment of their own abilities to perform activities of daily living (ADLs). We tested the hypothesis that postoperative changes in various measures of physical functioning do not vary by procedure.

Both objective and subjective assessments were used to measure changes in physical functioning. Objective functional assessments were conducted using isokinetic testing with either Cybex 6000 (Cybex Extremity Systems, Division of Lumex Corporation, Ronkonkoma, N.Y.) or Bidex (Biodex Corporation, Shirley, N.Y. devices. As an indicator of muscle strength, peak torque was measured isokinetically both pre-operatively and one year following reconstruction for shoulder flexion/extension as well as trunk flexion/extension. While shoulder flexion and extension were tested as speeds of 90 and 180 degrees per second, trunk flexion and extension were assessed at 30 and 90 degrees per second.

Functional outcomes were also subjectively evaluated by assessing patient's abilities to perform activities of daily living (ADLs). To survey ADLs, two previously validated and commonly used instruments were employed: the MOS Short Form Health Survey (SF-36) and the Functional Assessment of Cancer Therapy - Breast (Fact-B). Both questionnaires include items and subscales assessing overall physical functioning and ADLs. As with the isokinetic testing, the battery of questionnaires was administered pre-operatively and at one year following reconstruction.

Gainscores (difference between post- and pre-operative scores) were calculated using the isokinetic peak torque measurements for each muscle group in study subjects. Similarly, gainscores were also obtained for the SF-36, Fact-B and condition-specific sub-scales in each study participant. Analysis of covariance (ANCOVA) was performed to test for interactions between the independent variables of interest (reconstruction type and timing of procedure) and dependent variables (gainscores), controlling for base-line score.

Among the three study groups (implant, pedicle TRAM and free TRAM reconstructions), there were no statistically significant differences in demographic characteristics such as age, employment status, income, and health care payer observed.

Results of isokinetic testing varied according to the pre-set speeds of the dynamometer. For shoulder flexion and extension at 90 degrees per second, timing of reconstruction and baseline (preoperative) score produced effects of marginal statistical significance on mean change in peak torque (Δ PT) ($p=0.052$). However, no procedure effect (implant versus pedicle or free TRAM) was noted in mean Δ PT for shoulder flexion or extension at this speed. For shoulder flexion and extension at 180 degrees per second, interaction between procedure type and preoperative baseline produced a statistically significant effect on mean Δ PT ($p=0.016$). However, independent of baseline, procedure type did not have a significant effect on mean Δ PT for shoulder flexion and extension at 180 degrees per second.

Isokinetic testing of trunk flexion at 30 degrees per second demonstrated a highly significant effect for procedure type on mean Δ PT observed. This effect was highly significant ($p<0.001$) and independent of baseline scores. Overall, both pedicle and free TRAM reconstructions demonstrated declines in mean Δ PT compared with gains for the implant reconstruction cohort. Furthermore, the decreases noted were not significantly different for pedicle versus free TRAMs.

For trunk flexion at 90 degrees per second, findings demonstrated similar trends to those noted for the slower dynamometer speed. However, the interaction of procedure type with mean Δ PT was statistically marginal ($p=0.068$).

Assessment of trunk extension at both 30 and 90 degrees per second revealed no significant differences for changes in peak torque amount the three procedure types.

For both the SF-36 and FACT-B questionnaires, changes in levels of physical functioning as determined by ADLs were not significantly different for the three procedure types. Overall, regardless of procedure, postoperative ADL measures showed no significant decline in function compared with preoperative assessments. Although not statistically significant, all of the procedure groups registered gains in at least two of the three functional subscales.

In conclusion, the data suggest that, compared with implant techniques, both pedicle and free TRAM breast reconstructions may result in objectively measurable declines in abdominal wall function. However, these functional changes are not reflected in patients' subjective assessments of their abilities to perform routine ADLs. Furthermore, as indicated by both isokinetic testing and questionnaire results, free TRAMs may not offer relative functional advantages over pedicle TRAMs.

PATIENT SATISFACTION

In today's increasingly competitive health care marketplace, consumer satisfaction has become an important measure of quality. Furthermore, measures of satisfaction with treatment interventions are influential factors in determining patients' and payers' choices of health care. In this preliminary analysis of MBROS patient satisfaction data, we evaluated patient satisfaction with post mastectomy breast reconstruction and assessed the effects of procedure type and timing on patient satisfaction.

This preliminary analysis included 212 patients who had completed both the pre-operative and first year post-operative questionnaires. These questionnaires include a variety of health status questions as well as seven items assessing both general satisfaction with reconstruction (five items) and aesthetic satisfaction (two items) as separate subscales. Patients were asked to respond to each item using a five point Likert scale. Item responses ranged from 1, indicating high satisfaction, to 5, reflecting low satisfaction. In the data analysis, only patients responding with a 1 or 2 for all of the items within a subscale were classified as "satisfied" for the subscale. To assess the effects of procedure type (implant, pedicle TRAM or free TRAM) and timing (immediate versus delayed) on satisfaction, chi square tests were performed. In our analysis, statistical significance was defined as $p \leq 0.05$.

Of the 212 patients included in this analysis, 141 had immediate and 71 had delayed reconstructions. Among the study population, 49 received expander/implant reconstruction, 102 underwent pedicle TRAMs and 61 chose free TRAMs. Procedure type had a significant effect on both aesthetic satisfaction and general satisfaction. 75.2% of women with TRAMs (both pedicle and free) were very satisfied with their aesthetic results compared to 40.4% of women with implants ($p=.001$). Regarding satisfaction with overall outcome, 77.8% of women with TRAMs, compared to 61.2% of women with implants ($p=.021$) were very satisfied. Women with pedicle

TRAMs were not significantly different from women with free TRAMs on either satisfaction scale. Finally, no significant differences were noted in aesthetic or general satisfaction among women undergoing immediate and delayed reconstruction.

In conclusion, choice of procedure type appears to have a significant effect on both aesthetic and overall patient satisfaction with breast reconstruction. In this study, autogenous tissue reconstructions produced higher levels of patient satisfaction compared with implant techniques. By contrast, timing of breast reconstruction does not appear to be a significant determinant of patient satisfaction in these procedures.

CONCLUSION

In the next twelve months, work within MBROS will concentrate on several areas:

- (1) Continue administration of postoperative functional tests and questionnaires.
- (2) Continue collection of clinical data from participating hospitals and surgeons. Collect data on outpatient services from patients.
- (3) Continue collection of cost data from participating hospitals and surgeons. Continue collection of data on outpatient services from patients.
- (4) Conduct aesthetic evaluations of patients enrolled in months 1-24.
- (5) Perform data analysis.

As noted earlier, the objectives of MBROS are two-fold: (I.) to develop a standard set of instruments for the evaluation of outcomes from breast reconstruction; and (II.) to use these instruments to compare outcomes for patients undergoing expander/implant reconstruction and those receiving TRAM reconstruction. Significant progress towards achieving the project goals has been accomplished during the fourth year. Continuing present efforts to expand the study's patient population and maintaining adequate follow-up present the greatest challenges for the coming twelve months.

By accomplishing its objectives, MBROS will yield several important benefits. Instruments developed, refined and tested during the project can be used by other investigators for the ongoing monitoring of the quality of breast reconstruction. MBROS will yield information for use by patients and health care providers in selecting breast reconstruction procedures. Finally, completion of the project will produce a multicenter database for ongoing studies on the long-term outcomes of breast reconstruction.

PRESENTATIONS

- Wilkins EG, "Update on the Michigan Breast Reconstruction Outcome Study": Breast Surgery in the Nineties. Symposium Sponsored by the Plastic Surgery Educational Foundation. January, 1995, Atlanta, Georgia
- Wilkins EG, "Outcomes Research in Breast Surgery": Breast Surgery in the Nineties. Symposium Sponsored by the Plastic Surgery Educational Foundation. January, 1995, Atlanta, Georgia
- Wilkins EG, "Analysis of Instruments for Assessment of Aesthetic Outcomes in Breast Reconstruction." 11th Annual Plastic Surgery Educational Foundation, Breast Surgery Symposium. Atlanta, Georgia, January, 1995.
- Wilkins EG, "Outcomes Research in Breast Surgery." 11th Annual Plastic Surgery Educational Foundation Breast Surgery Symposium. Atlanta, Georgia, January, 1995.
- Wilkins EG, "Update on the Michigan Breast Reconstruction Outcome Study (MBROS)." 12th Annual Plastic Surgery Educational Foundation, Breast Surgery Symposium, Atlanta, Georgia, January, 1996.
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- Wilkins EG, "Comparisons of Functional Outcomes in Post Mastectomy Breast Reconstruction." 1997 Arkansas Plastic Surgery Symposium, Stuttgart, Arkansas, December, 1996.
- Wilkins EG, "Comparisons of Functional Outcomes in Post Mastectomy Breast Reconstruction." Plastic Surgery Research Council. 42nd Annual Meeting, Galveston, Texas, February, 1997.
- Cederna PS, "A Prospective Analysis of the Psychosocial Effects of Postmastectomy Breast Reconstruction." 1997 Plastic Surgery Senior Residents Conference, Sacramento, California, April, 1997. Awarded *Best Scientific Paper* for Senior Residents Conference.
- Wilkins EG, "Functional Outcomes in Post-Mastectomy Breast Reconstruction." American Association of Plastic Surgeons. 76th Annual Meeting, Portland, Oregon, May 20, 1997.
- Wilkins EG, "Update on the Michigan Breast Reconstruction Outcome Study." Plastic Surgery Educational Foundation Outcomes Symposium. Chicago, Illinois, July 12, 1997.
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- Cederna PS, "Prospective Analysis of Psychosocial Outcomes in Postmastectomy Breast Reconstruction." American College of Surgeons Annual Clinical Congress, Chicago, Illinois, October, 1997.

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Alderman, A, "Determinants of Patient Satisfaction in post-Mastectomy Breast Reconstruction." Michigan Adacemy of Plastic Surgeons, 1998 Summer Scientific Meeting, Mackinac Island, Michigan, July 12 -15, 1998

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ATTACHMENT A

PRE-SURGERY AND POST-SURGERY EVALUATION FORMS

Pre-Surgery Evaluation
Michigan Breast Reconstruction Outcome Study
University of Michigan, Ann Arbor

(For office use only)
REGISTRATION #

I. Personal Information

Today's Date: _____

Your Name: _____

Date of Birth: _____ SS#: _____

Address: _____

City, State, Zip: _____

Telephone: (home) _____ - _____ - _____ (work) _____ - _____ - _____

Contact person or relative who does not live with you:

Name _____

Telephone: (home) _____ - _____ - _____

With regards to your mastectomy:

Date of Mastectomy _____ General Surgeon's name _____

Hospital Name _____ City, State _____

Decision to Seek Surgery

We are interested in why you have chosen to seek breast reconstruction. The following statements reflect some of the reasons why women seek breast reconstruction following a mastectomy. For each statement, please circle the one answer that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I want to feel whole again.	1	2	3	4	5
2. I want to feel the way I did before my cancer.	1	2	3	4	5
3. I want to wear the same type of clothing I was able to before my breast cancer.	1	2	3	4	5
4. I want to feel attractive.	1	2	3	4	5
5. I want to avoid the need to wear a prosthesis.	1	2	3	4	5
6. I want to have breast reconstruction so that I am not constantly reminded that I had cancer.	1	2	3	4	5
7. I am having surgery mainly because my significant other wants me to.	1	2	3	4	5
8. I want to be more attractive to my significant other.	1	2	3	4	5
9. I want to feel less self-conscious during sexual activity.	1	2	3	4	5
10. I want to improve my relationship with my significant other.	1	2	3	4	5
11. I think that breast reconstruction will enhance my emotional health and self-worth.	1	2	3	4	5

General Health Survey

1. In general, would you say your health is: (Circle One Number)

Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now?

(Circle One Number)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

In one year from now, how do you think your health will be?

(Circle One Number)

Much better than today	1
Somewhat better than today	2
About the same as today	3
Somewhat worse than today	4
Much worse than today	5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle One Number on Each Line)	Yes Limited a Lot	Yes Limited a Little	Not Limited at All
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling or stooping	1	2	3
9. Walking more than one mile	1	2	3
10. Walking several blocks	1	2	3
11. Walking one block	1	2	3
12. Bathing or dressing yourself	1	2	3
13. Bending over to brush your teeth	1	2	3
14. Sitting up in bed when you awake in the morning	1	2	3
15. Doing the dishes	1	2	3
16. Arising from a chair	1	2	3
17. Grasping for something, like reaching for a glass from the cupboard	1	2	3

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(Circle One Number on Each Line)	Yes	No
18. Cut down the amount of time you spent on work or other activities	1	2
19. Accomplished less than you would like	1	2
20. Were limited in the kind of work or other activities	1	2
21. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Circle One Number on Each Line)	Yes	No
22. Cut down the amount of time you spent on work or other activities	1	2
23. Accomplished less than you would like	1	2
24. Didn't do work or other activities as carefully as usual	1	2

25. During the **past four weeks**, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

(Circle One Number)
Not at all
Slightly
Moderately
Quite a bit
Extremely

26. How much **bodily** pain have you had during the **past four weeks**?

(Circle One Number)
None
Very mild
Mild
Moderate
Severe
Very severe

27. During the **past four weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework?)

(Circle One Number)
Not at all
A little bit
Moderately
Quite a bit
Extremely

For each of the following statements, please circle the one answer that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True 1	Mostly True 2	Not Sure 3	Mostly False 4	Definitely False 5
28. My breasts are without pain.					
29. My abdomen is sore and painful.	1	2	3	4	5
30. I am frequently troubled by headaches.	1	2	3	4	5
31. My abdomen feels tight.	1	2	3	4	5
32. I have back pain.	1	2	3	4	5

These questions are about how you feel and how things have been with you **during the past four weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past four weeks** . . .

(Circle One Number on Each Line)	All of the Time 1	Most of the Time 2	A Good Bit of the Time 3	Some of the Time 4	A Little of the Time 5	None of the Time 6
33. Did you feel full of pep?	1	2	3	4	5	6
34. Have you been a very nervous person?	1	2	3	4	5	6
35. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
36. Have you felt calm and peaceful?	1	2	3	4	5	6
37. Did you have a lot of energy?	1	2	3	4	5	6
38. Have you felt downhearted and blue?	1	2	3	4	5	6
39. Did you feel worn out?	1	2	3	4	5	6
40. Have you been a happy person?	1	2	3	4	5	6
41. Did you feel tired?	1	2	3	4	5	6

42. During the **past four weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How TRUE or FALSE is each of the following statements for you?

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
43. I seem to get sick a little easier than other people.	1	2	3	4	5
44. I am as healthy as anybody I know.	1	2	3	4	5
45. I expect my health to get worse.	1	2	3	4	5
46. My health is excellent.	1	2	3	4	5

Personal Beliefs

The following items describe feelings that one may have about their appearance and attractiveness. Please circle the number that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
47. I believe that physical attractiveness is important in day-to-day social interaction.	1	2	3	4	5
48. I believe that physical attractiveness is important in acquiring a mate (e.g., spouse, significant other).	1	2	3	4	5
49. I believe that physical attractiveness is important in attracting a sexual partner.	1	2	3	4	5
50. My breasts have always been an important part of my sexuality.	1	2	3	4	5
51. Physical and sexual attractiveness have always been very important to me.	1	2	3	4	5

The following items relate specifically to your feelings about the appearance of your breasts. Please circle the answer that best describes the way you now feel.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I feel whole.	1	2	3	4	5
2. I like the way my blouses/sweaters fit.	1	2	3	4	5
3. I like the way I look in a bathing suit.	1	2	3	4	5
4. My bra fits comfortably.	1	2	3	4	5
5. I feel attractive.	1	2	3	4	5
6. I think of my cancer when I look at my breasts.	1	2	3	4	5
7. I like the appearance of my breasts.	1	2	3	4	5
8. My significant other likes the appearance of my breasts.	1	2	3	4	5
9. I feel self-conscious during sexual activity because of the appearance of my breasts.	1	2	3	4	5

Health Complaints

1. The following items describe bodily symptoms that most of us have experienced at one time or another. Please circle the number that corresponds best with the way you have felt during the PAST WEEK. Please answer all questions. Do not think too long before answering.

	Not at all	A little/slightly	A great deal/quite a bit	Extremely could not have been worse
Heart rate increase	1	2	3	4
Feeling hot all over	1	2	3	4
Sweating all over	1	2	3	4
Sweating in a particular part of the body	1	2	3	4
Pulse in neck	1	2	3	4
Pounding in head	1	2	3	4
Dizziness	1	2	3	4
Blurring of vision	1	2	3	4
Feeling faint	1	2	3	4
Everything appearing unreal	1	2	3	4
Nausea	1	2	3	4
Butterflies in stomach	1	2	3	4
Pain or ache in stomach	1	2	3	4
Stomach churning	1	2	3	4
Desire to pass water	1	2	3	4
Mouth becoming dry	1	2	3	4
Difficulty swallowing	1	2	3	4
Muscles in neck aching	1	2	3	4
Legs feeling weak	1	2	3	4
Muscles twitching or jumping	1	2	3	4
Tense feeling across forehead	1	2	3	4
Tense feeling in jaw muscles	1	2	3	4

2. Here is a list of health problems that usually last for some time. Do you have any of the following problems? (Check all that apply)

Yes No

- Asthma
- Chronic bronchitis or emphysema
- Arthritis or rheumatism
- High blood pressure
- Angina
- Congestive heart failure
- History of stroke
- Cancer (other than breast or skin cancer: specify type _____)
- Diabetes
- Chronic back trouble
- Lupus
- Scleroderma
- Other _____

We would like to learn more about you and your background. Please answer the following questions so that we may better understand your responses.

1. Do you consider yourself primarily:

- African-American
- Asian or Pacific Islander
- Hispanic
- Native American
- White
- Other (please specify): _____

2. Highest level of education completed?

- Less than high school
- Completed high school
- Some college
- Completed college
- Some graduate work
- Graduate degree

3. Please check the best description of your current marital situation.

- Single
- Living with a significant other
- Married
- Widowed
- Divorced
- Separated

4. We are interested in knowing the degree to which you have participated in regular exercise habits DURING THE PAST SIX MONTHS. The following examples list various exercise activities in terms of their vigorousness and duration.

MILD EXERCISE: leisurely walking, gardening, leisurely biking.

MODERATE EXERCISE: 30 minutes or less of low-impact aerobics, jogging, tennis, biking, swimming, etc.

VIGOROUS EXERCISE: 30 minutes or more of aerobics, running, basketball, stair-stepper, etc.

Please review the following statements and select the one answer which best describes your exercise habits over the past six months.

- I do not exercise
- I do mild exercise 1 to 2 times per week
- I do mild exercise 3 or more times per week
- I do moderate exercise 1 to 2 times per week
- I do moderate exercise 3 or more times per week
- I do vigorous exercise 1 to 2 times per week
- I do vigorous exercise 3 or more times per week

- 4a. When did you take part in the physical activity or exercise which you checked in Question 4, for how long did you usually maintain it?

- 15 minutes or less
- Greater than 15 minutes, but less than 45 minutes
- 45 minutes or more
- I do not exercise

5. Now we are interested in whether or not your exercise routine includes abdominal/stomach and back exercises, such as sit-ups or curl-ups. During the past six months, on average, how many times per week did you specifically exercise your back or stomach muscles?

- Not at all
- Once a week or less
- Two to three times per week
- More than three times per week

6. Do you currently smoke cigarettes? Yes _____ No _____

7. If you smoke cigarettes, how many packages of cigarettes do you smoke in an average day?

- less than 1/2 pack per day
- 1/2 to 1 pack per day
- more than 1 pack per day

8. Do you currently drink any alcoholic beverages (beer, wine, liquor)? Yes _____ No _____

9. If you currently do drink alcoholic beverages, how many drinks do you consume in an average week (including the weekend)? _____

10. Please check the statement that best describes your current employment situation:
Read all options carefully before checking just one.

- I am currently employed outside of the home, or am seeking employment outside of the home
- I am currently employed outside of the home, on paid or unpaid leave
- I am a homemaker, student, or retired person
- I am disabled due to my breast cancer
- I am disabled but not due to my breast cancer
- Other (please specify): _____

11. If you are currently working outside of the home, how many hours per week do you spend on that work?

- Not currently working outside of the home
- Less than 15 hours per week
- 15 to 40 hours per week
- More than 40 hours per week

12. Which of the following best describes your work history?

- I have not worked in the past three years
- I have worked intermittently for the past three years
- I have been continuously employed for the past three years

13. What type(s) of medical insurance coverage do you carry?

(Check yes or no for each one.)

Yes No

Blue Cross/Blue Shield

Other Private Insurance (e.g., Aetna, Travelers, etc.)

HMO or Managed Care program (which? _____)

Medicare

Medicaid

None

Other (Which? _____)

14. Does the medical insurance which you carry cover breast reconstruction surgery?

Yes _____ No _____ Don't Know _____

15. About what was your total family income from all sources last year before taxes? (Count all income for all household members who live with you. Circle one number for the category that includes your approximate family income last year.)

(Circle one number)

- | | |
|----------------------|---|
| less than \$15,000 | 1 |
| \$15,000 to \$24,999 | 2 |
| \$25,000 to \$49,999 | 3 |
| \$50,000 to \$75,000 | 4 |
| more than \$75,000 | 5 |

16. How many persons other than yourself are dependent on your family's income? _____

Fact-B (Version 3)

Michigan Breast Reconstruction Outcome Study University of Michigan, Ann Arbor

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past seven days.

During the past seven days:

Physical Well-Being

1.	I have a lack of energy.	0	1	2	3	4
2.	I have nausea.	0	1	2	3	4
3.	Because of my physical condition, I have trouble meeting the needs of my family.	0	1	2	3	4
4.	I have pain.	0	1	2	3	4
5.	I am bothered by side effects of treatment.	0	1	2	3	4
6.	I feel sick.	0	1	2	3	4
7.	I am forced to spend time in bed.	0	1	2	3	4
8.	Looking at the above seven questions, how much would you say your Physical Well-Being affects your quality of life?					

(circle one number)

During the past seven days:

Social/Family Well-Being

9. I feel distant from my friends. 0 1 2 3 4
10. I get emotional support from my family. 0 1 2 3 4
11. I get support from my friends and neighbors. 0 1 2 3 4
12. My family has accepted my illness. 0 1 2 3 4
13. Family communication about my illness is poor. 0 1 2 3 4
14. I feel close to my partner
(or the person who is my main support). 0 1 2 3 4

15. Have you been sexually active during the past year?
No
Yes If yes: I am satisfied with my sex life. 0 1 2 3 4

No

Yes If yes: I am satisfied with my sex life.

0 1 2 3 4

16. Looking at the above seven questions, how much would you say your **Social/Family Well-Being** affects your quality of life?

(circle one number)

During the past seven days:

Additional Concerns

	not at all	a little bit	some what	quite a bit	very much
--	---------------	-----------------	--------------	----------------	--------------

- | | | | | | |
|--|---|---|---|---|---|
| 35. I have been short of breath. | 0 | 1 | 2 | 3 | 4 |
| 36. I am self-conscious about the way I dress. | 0 | 1 | 2 | 3 | 4 |
| 37. My arms are swollen or tender. | 0 | 1 | 2 | 3 | 4 |
| 38. I feel sexually attractive. | 0 | 1 | 2 | 3 | 4 |
| 39. I have been bothered by hair loss. | 0 | 1 | 2 | 3 | 4 |
| 40. I worry about the risk of cancer in other family
members. | 0 | 1 | 2 | 3 | 4 |
| 41. I worry about the effect of stress on my illness. | 0 | 1 | 2 | 3 | 4 |
| 42. I am bothered by a change in weight. | 0 | 1 | 2 | 3 | 4 |
| 43. I am able to feel like a woman. | 0 | 1 | 2 | 3 | 4 |

44. Looking at the above nine questions, how much would you say these **Additional Concerns** affect your quality of life?

(circle one number)

0	1	2	3	4	5	6	7	8	9	10
not at all					very much					

INSTRUCTIONS:

Below is a list of problems people sometimes have. Please read each one carefully, and circle the number to the right that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST SEVEN DAYS, INCLUDING TODAY. Circle only one number for each problem, and do not skip any items. If you change your mind, erase your first mark carefully.

HOW MUCH WERE YOU DISTRESSED BY:

		Not At All	A Little Bit	Moderately	Quite A Bit	Extremely
1. Nervousness or shakiness inside	1	0	1	2	3	4
2. Faintness or dizziness	2	0	1	2	3	4
3. The idea that someone else can control your thoughts	3	0	1	2	3	4
4. Feeling others are to blame for most of your troubles	4	0	1	2	3	4
5. Trouble remembering things	5	0	1	2	3	4
6. Feeling easily annoyed or irritated	6	0	1	2	3	4
7. Pains in heart or chest	7	0	1	2	3	4
8. Feeling afraid in open spaces	8	0	1	2	3	4
9. Thoughts of ending your life	9	0	1	2	3	4
10. Feeling that most people cannot be trusted	10	0	1	2	3	4
11. Poor appetite	11	0	1	2	3	4
12. Suddenly scared for no reason	12	0	1	2	3	4
13. Temper outbursts that you could not control	13	0	1	2	3	4
14. Feeling lonely even when you are with people	14	0	1	2	3	4
15. Feeling blocked in getting things done	15	0	1	2	3	4
16. Feeling lonely	16	0	1	2	3	4
17. Feeling blue	17	0	1	2	3	4
18. Feeling no interest in things	18	0	1	2	3	4
19. Feeling fearful	19	0	1	2	3	4
20. Your feelings being easily hurt	20	0	1	2	3	4
21. Feeling that people are unfriendly or dislike you	21	0	1	2	3	4
22. Feeling inferior to others	22	0	1	2	3	4
23. Nausea or upset stomach	23	0	1	2	3	4
24. Feeling that you are watched or talked about by others	24	0	1	2	3	4
25. Trouble falling asleep	25	0	1	2	3	4
26. Having to check and double check what you do	26	0	1	2	3	4
27. Difficulty making decisions	27	0	1	2	3	4
28. Feeling afraid to travel on buses, subways or trains	28	0	1	2	3	4
29. Trouble catching your breath	29	0	1	2	3	4
30. Hot or cold spells	30	0	1	2	3	4
31. Having to avoid certain things, places or activities because they frighten you	31	0	1	2	3	4
32. Your mind going blank	32	0	1	2	3	4
33. Numbness or tingling in parts of your body	33	0	1	2	3	4
34. The idea that you should be punished for your sins	34	0	1	2	3	4
35. Feeling hopeless about the future	35	0	1	2	3	4

HOW MUCH WERE YOU DISTRESSED BY:

Extremely
Quite A Bit
Moderately
A Little Bit
Not At All

		Not At All	A Little Bit	Moderately	Quite A Bit	Extremely
36. Trouble concentrating	36	0	1	2	3	4
37. Feeling weak in parts of your body	37	0	1	2	3	4
38. Feeling tense or keyed up	38	0	1	2	3	4
39. Thoughts of death or dying	39	0	1	2	3	4
40. Having urges to beat, injure or harm someone	40	0	1	2	3	4
41. Having urges to break or smash things	41	0	1	2	3	4
42. Feeling very self-conscious with others	42	0	1	2	3	4
43. Feeling uneasy in crowds	43	0	1	2	3	4
44. Never feeling close to another person	44	0	1	2	3	4
45. Spells of terror or panic	45	0	1	2	3	4
46. Getting into frequent arguments	46	0	1	2	3	4
47. Feeling nervous when you are left alone	47	0	1	2	3	4
48. Others not giving you proper credit for your achievements	48	0	1	2	3	4
49. Feeling so restless you couldn't sit still	49	0	1	2	3	4
50. Feelings of worthlessness	50	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	51	0	1	2	3	4
52. Feelings of guilt	52	0	1	2	3	4
53. The idea that something is wrong with your mind	53	0	1	2	3	4



Post-Surgery Evaluation

Michigan Breast Reconstruction Outcome Study
University of Michigan, Ann Arbor

(For office use only)
REGISTRATION #

I. Personal Information

Today's Date: _____

Your Name: _____

Date of Birth: _____ SS#: _____

Address: _____

City, State, Zip: _____

Telephone: (home) _____ - _____ - _____ (work) _____ - _____ - _____

Contact person or relative who does not live with you:

Name _____

Telephone: (home) _____ - _____ - _____

Satisfaction with Surgery

	Definitely <u>True</u>	Mostly <u>True</u>	Not <u>Sure</u>	Mostly <u>False</u>	Definitely <u>False</u>
1. Knowing what I know today, I would definitely choose to have breast reconstruction .	1	2	3	4	5
2. Knowing what I know today, I would definitely choose to have the <u>type</u> of reconstruction I had.	1	2	3	4	5
3. The size and shape of my breasts are the same.	1	2	3	4	5
4. My reconstructed breast(s) feel soft to the touch.	1	2	3	4	5
5. Overall, I am satisfied with my reconstruction.	1	2	3	4	5
6. I would recommend the type of reconstructive procedure that I had to a friend.	1	2	3	4	5
7. I felt that I received sufficient information about my reconstruction options to make an informed choice of either the TRAM or Implant procedure.	1	2	3	4	5

General Health Survey

1. In general, would you say your health is: (Circle One Number)

- | | |
|-----------|---|
| Excellent | 1 |
| Very Good | 2 |
| Good | 3 |
| Fair | 4 |
| Poor | 5 |

2. Compared to one year ago, how would you rate your health in general now?

(Circle One Number)

- | | |
|---------------------------------------|---|
| Much better now than one year ago | 1 |
| Somewhat better now than one year ago | 2 |
| About the same | 3 |
| Somewhat worse now than one year ago | 4 |
| Much worse now than one year ago | 5 |

In one year from now, how do you think your health will be?

(Circle One Number)

- | | |
|----------------------------|---|
| Much better than today | 1 |
| Somewhat better than today | 2 |
| About the same as today | 3 |
| Somewhat worse than today | 4 |
| Much worse than today | 5 |

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)	Yes Limited a Lot	Yes Limited a Little	Not Limited at All
3. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling or stooping	1	2	3
9. Walking more than one mile	1	2	3
10. Walking several blocks	1	2	3
11. Walking one block	1	2	3
12. Bathing or dressing yourself	1	2	3
13. Bending over to brush your teeth	1	2	3
14. Sitting up in bed when you awake in the morning	1	2	3
15. Doing the dishes	1	2	3
16. Arising from a chair	1	2	3
17. Grasping for something, like reaching for a glass from the cupboard	1	2	3

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)	Yes	No
18. Cut down the amount of time you spent on work or other activities	1	2
19. Accomplished less than you would like	1	2
20. Were limited in the kind of work or other activities	1	2
21. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)	Yes	No
22. Cut down the amount of time you spent on work or other activities	1	2
23. Accomplished less than you would like	1	2
24. Didn't do work or other activities as carefully as usual	1	2

25. During the **past four weeks**, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

(Circle One Number)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

26. How much **body** pain have you had during the **past four weeks**?

(Circle One Number)

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

27. During the **past four weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

For each of the following statements, please circle the one answer that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
28. My breasts are without pain.	1	2	3	4	5
29. My abdomen is sore and painful.	1	2	3	4	5
30. I am frequently troubled by headaches.	1	2	3	4	5
31. My abdomen feels tight.	1	2	3	4	5
32. I have back pain.	1	2	3	4	5

These questions are about how you feel and how things have been with you **during the past four weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past four weeks** . . .

(Circle One Number on Each Line)	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
33. Did you feel full of pep?	1	2	3	4	5	6
34. Have you been a very nervous person?	1	2	3	4	5	6
35. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
36. Have you felt calm and peaceful?	1	2	3	4	5	6
37. Did you have a lot of energy?	1	2	3	4	5	6
38. Have you felt downhearted and blue?	1	2	3	4	5	6
39. Did you feel worn out?	1	2	3	4	5	6
40. Have you been a happy person?	1	2	3	4	5	6
41. Did you feel tired?	1	2	3	4	5	6

42. During the **past four weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How TRUE or FALSE is each of the following statements for you?

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
43. I seem to get sick a little easier than other people.	1	2	3	4	5
44. I am as healthy as anybody I know.	1	2	3	4	5
45. I expect my health to get worse.	1	2	3	4	5
46. My health is excellent.	1	2	3	4	5

Personal Beliefs

The following items describe feelings that one may have about their appearance and attractiveness. Please circle the number that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
47. I believe that physical attractiveness is important in day-to-day social interaction.	1	2	3	4	5
48. I believe that physical attractiveness is important in acquiring a mate (e.g., spouse, significant other).	1	2	3	4	5
49. I believe that physical attractiveness is important in attracting a sexual partner.	1	2	3	4	5
50. My breasts have always been an important part of my sexuality.	1	2	3	4	5
51. Physical and sexual attractiveness have always been very important to me.	1	2	3	4	5

The following items relate specifically to your feelings about the appearance of your breasts. Please circle the answer that best describes the way you now feel.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I feel whole.	1	2	3	4	5
2. I like the way my blouses/sweaters fit.	1	2	3	4	5
3. I like the way I look in a bathing suit.	1	2	3	4	5
4. My bra fits comfortably.	1	2	3	4	5
5. I feel attractive.	1	2	3	4	5
6. I think of my cancer when I look at my breasts.	1	2	3	4	5
7. I like the appearance of my breasts.	1	2	3	4	5
8. My significant other likes the appearance of my breasts.	1	2	3	4	5
9. I feel self-conscious during sexual activity because of the appearance of my breasts.	1	2	3	4	5

Health Complaints

1. The following items describe bodily symptoms that most of us have experienced at one time or another. Please circle the number that corresponds best with the way you have felt during the PAST WEEK. Please answer all questions. Do not think too long before answering.

	Not at all	A little/slightly	A great deal/quite a bit	Extremely could not have been worse
Heart rate increase	1	2	3	4
Feeling hot all over	1	2	3	4
Sweating all over	1	2	3	4
Sweating in a particular part of the body	1	2	3	4
Pulse in neck	1	2	3	4
Pounding in head	1	2	3	4
Dizziness	1	2	3	4
Blurring of vision	1	2	3	4
Feeling faint	1	2	3	4
Everything appearing unreal	1	2	3	4
Nausea	1	2	3	4
Butterflies in stomach	1	2	3	4
Pain or ache in stomach	1	2	3	4
Stomach churning	1	2	3	4
Desire to pass water	1	2	3	4
Mouth becoming dry	1	2	3	4
Difficulty swallowing	1	2	3	4
Muscles in neck aching	1	2	3	4
Legs feeling weak	1	2	3	4
Muscles twitching or jumping	1	2	3	4
Tense feeling across forehead	1	2	3	4
Tense feeling in jaw muscles	1	2	3	4

2. Here is a list of health problems that usually last for some time. Do you have any of the following problems? (Check all that apply)

Yes No

- Asthma
 Chronic bronchitis or emphysema
 Arthritis or rheumatism
 High blood pressure
 Angina
 Congestive heart failure
 History of stroke
 Cancer (other than breast or skin cancer: specify type _____)
 Diabetes
 Chronic back trouble
 Lupus
 Scleroderma
 Other _____

3. Approximately how many times during the PAST SIX MONTHS have you had to visit a doctor because of physical symptoms or follow-up care **related** to your breast reconstruction? Please check one of the following.
- 5 or less times
 6 to 10 times
 More than 10 times
4. Approximately how many times during the PAST SIX MONTHS have you had to visit a doctor because of physical symptoms related to treatment for medical problems **unrelated** to your breast cancer or to your reconstruction? Please check one of the following.
- 5 or less times
 6 to 10 times
 More than 10 times

We would like to learn more about you and your background. Please answer the following questions so that we may better understand your responses.

1. Please check the best description of your current marital situation.

Single
 Living with a significant other
 Married
 Widowed
 Divorced
 Separated
2. We are interested in knowing the degree to which you have participated in regular exercise habits DURING THE PAST SIX MONTHS. The following examples list various exercise activities in terms of their vigorousness and duration.

MILD EXERCISE: leisurely walking, gardening, leisurely biking.

MODERATE EXERCISE: 30 minutes or less of low-impact aerobics, jogging, tennis, biking, swimming, etc.

VIGOROUS EXERCISE: 30 minutes or more of aerobics, running, basketball, stair-stepper, etc.

Please review the following statements and select the one answer which best describes your exercise habits over the past six months.

- I do not exercise
 I do mild exercise 1 to 2 times per week
 I do mild exercise 3 or more times per week
 I do moderate exercise 1 to 2 times per week
 I do moderate exercise 3 or more times per week
 I do vigorous exercise 1 to 2 times per week
 I do vigorous exercise 3 or more times per week
3. When you did take part in the physical activity or exercise which you checked in Questions 4, for how long did you usually maintain it?

15 minutes or less
 Greater than 15 minutes, but less than 45 minutes
 45 minutes or more
 I do not exercise
 4. Now we are interested in whether or not your exercise routine includes abdominal/stomach and back exercises, such as sit-ups or curl-ups. During the past six months, on average, how many times per week did you specifically exercise your back or stomach muscles?

Not at all
 Once a week or less
 Two to three times per week
 More than three times per week

5. Do you currently smoke cigarettes? Yes ____ No ____
6. If you smoke cigarettes, how many packages of cigarettes do you smoke in an average day?
____ less than 1/2 pack per day
____ 1/2 to 1 pack per day
____ more than 1 pack per day
7. Do you currently drink any alcoholic beverages (beer, wine, liquor)? Yes ____ No ____
8. If you currently do drink alcoholic beverages, how many drinks do you consume in an average week (including the weekend)? _____
9. Please check the statement that best describes your current employment situation:
Read all options carefully before checking just one.
____ I am currently employed outside of the home,
or am seeking employment outside of the home
____ I am currently employed outside of the home, on paid or unpaid leave
____ I am a homemaker, student, or retired person
____ I am disabled due to my breast cancer
____ I am disabled but not due to my breast cancer
____ Other (please specify): _____
10. If you are currently working outside of the home, how many hours per week do you spend on that work?
____ Not currently working outside of the home
____ Less than 15 hours per week
____ 15 to 40 hours per week
____ More than 40 hours per week
11. Which of the following best describes your work history?
____ I have not worked in the past three years
____ I have worked intermittently for the past three years
____ I have been continuously employed for the past three years
12. If you were employed prior to breast reconstruction, what impact has the reconstruction had on your employment?
____ It has not been affected
____ I had to reduce my hours or type of work
____ I have left my job.

13. About what was your total family income from all sources last year before taxes? (Count all income for all household members who live with you. Circle one number for the category that includes your approximate family income last year.)

(Circle one number)	
less than \$15,000	1
\$15,000 to \$24,999	2
\$25,000 to \$49,999	3
\$50,000 to \$75,000	4
more than \$75,000	5

14. How many persons other than yourself are dependent on your family's income? _____

Fact-B (Version 3)

Michigan Breast Reconstruction Outcome Study University of Michigan, Ann Arbor

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past seven days.

During the past seven days:

Physical Well-Being

1. I have a lack of energy.	0	1	2	3	4
2. I have nausea.	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family.	0	1	2	3	4
4. I have pain.	0	1	2	3	4
5. I am bothered by side effects of treatment.	0	1	2	3	4
6. I feel sick.	0	1	2	3	4
7. I am forced to spend time in bed.	0	1	2	3	4

8. Looking at the above seven questions, how much would you say your **Physical Well-Being** affects your quality of life?

(circle one number)

During the past seven days:

Social/Family Well-Being

9. I feel distant from my friends.	0	1	2	3	4
10. I get emotional support from my family.	0	1	2	3	4
11. I get support from my friends and neighbors.	0	1	2	3	4
12. My family has accepted my illness.	0	1	2	3	4
13. Family communication about my illness is poor.	0	1	2	3	4
14. I feel close to my partner (or the person who is my main support).	0	1	2	3	4

15. Have you been sexually active during the past year?

No

Yes If yes: I am satisfied with my sex life.

0 1 2 3 4

16. Looking at the above seven questions, how much would you say your **Social/Family Well-Being** affects your quality of life?

(circle one number)

During the past seven days: **Relationship With The Doctor**

not a little some quite very
at all bit what a bit much

17. I have confidence in my doctor(s). 0 1 2 3 4
18. My doctor is available to answer my questions. 0 1 2 3 4

19. Looking at the above two questions, how much would you say your **Relationship With The Doctor** affects your quality of life?

(circle one number)

During the past seven days: **Emotional Well-Being**

not a little some quite very
at all bit what a bit much

20. I feel sad.	0	1	2	3	4
21. I am proud of how I'm coping with my illness.	0	1	2	3	4
22. I am losing hope in the fight against my illness.	0	1	2	3	4
23. I feel nervous.	0	1	2	3	4
24. I worry about dying.	0	1	2	3	4
25. I worry that my condition will get worse.	0	1	2	3	4

26. Looking at the above six questions, how much would you say your **Emotional Well-Being** affects your quality of life?

(circle one number)

During the past seven days:
Functional Well-Being

not a little some quite very
at all bit what a bit much

27. I am able to work (include the work in home).	0	1	2	3	4
28. My work (include work in home) is fulfilling.	0	1	2	3	4
29. I am able to enjoy life.	0	1	2	3	4
30. I have accepted my illness.	0	1	2	3	4
31. I am sleeping well.	0	1	2	3	4
32. I am enjoying the things I usually do for fun.	0	1	2	3	4
33. I am content with the quality of my life right now.	0	1	2	3	4

34. Looking at the above seven questions, how much would you say your **Functional Well-Being** affects your quality of life?

(circle one number)

During the past seven days:

Additional Concerns

During the past seven days: Additional Concerns	not at all	a little bit	some what	quite a bit	very much
35. I have been short of breath.	0	1	2	3	4
36. I am self-conscious about the way I dress.	0	1	2	3	4
37. My arms are swollen or tender.	0	1	2	3	4
38. I feel sexually attractive.	0	1	2	3	4
39. I have been bothered by hair loss.	0	1	2	3	4
40. I worry about the risk of cancer in other family members.	0	1	2	3	4
41. I worry about the effect of stress on my illness.	0	1	2	3	4
42. I am bothered by a change in weight.	0	1	2	3	4
43. I am able to feel like a woman.	0	1	2	3	4

44. Looking at the above nine questions, how much would you say these **Additional Concerns** affect your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10

not at all

very much

INSTRUCTIONS:

Below is a list of problems people sometimes have. Please read each one carefully, and circle the number to the right that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST SEVEN DAYS, INCLUDING TODAY. Circle only one number for each problem, and do not skip any items. If you change your mind, erase your first mark carefully.

HOW MUCH WERE YOU DISTRESSED BY:		<i>Not At All</i>	<i>A Little Bit</i>	<i>Moderately</i>	<i>Quite A Bit</i>	<i>Extremely</i>
1.	Nervousness or shakiness inside	1	0	1	2	3
2.	Faintness or dizziness	2	0	1	2	3
3.	The idea that someone else can control your thoughts	3	0	1	2	3
4.	Feeling others are to blame for most of your troubles	4	0	1	2	3
5.	Trouble remembering things	5	0	1	2	3
6.	Feeling easily annoyed or irritated	6	0	1	2	3
7.	Pains in heart or chest	7	0	1	2	3
8.	Feeling afraid in open spaces	8	0	1	2	3
9.	Thoughts of ending your life	9	0	1	2	3
10.	Feeling that most people cannot be trusted	10	0	1	2	3
11.	Poor appetite	11	0	1	2	3
12.	Suddenly scared for no reason	12	0	1	2	3
13.	Temper outbursts that you could not control	13	0	1	2	3
14.	Feeling lonely even when you are with people	14	0	1	2	3
15.	Feeling blocked in getting things done	15	0	1	2	3
16.	Feeling lonely	16	0	1	2	3
17.	Feeling blue	17	0	1	2	3
18.	Feeling no interest in things	18	0	1	2	3
19.	Feeling fearful	19	0	1	2	3
20.	Your feelings being easily hurt	20	0	1	2	3
21.	Feeling that people are unfriendly or dislike you	21	0	1	2	3
22.	Feeling inferior to others	22	0	1	2	3
23.	Nausea or upset stomach	23	0	1	2	3
24.	Feeling that you are watched or talked about by others	24	0	1	2	3
25.	Trouble falling asleep	25	0	1	2	3
26.	Having to check and double check what you do	26	0	1	2	3
27.	Difficulty making decisions	27	0	1	2	3
28.	Feeling afraid to travel on buses, subways or trains	28	0	1	2	3
29.	Trouble catching your breath	29	0	1	2	3
30.	Hot or cold spells	30	0	1	2	3
31.	Having to avoid certain things, places or activities because they frighten you	31	0	1	2	3
32.	Your mind going blank	32	0	1	2	3
33.	Numbness or tingling in parts of your body	33	0	1	2	3
34.	The idea that you should be punished for your sins	34	0	1	2	3
35.	Feeling hopeless about the future	35	0	1	2	3

HOW MUCH WERE YOU DISTRESSED BY:

		<i>Not At All</i>	<i>A Little Bit</i>	<i>Moderately</i>	<i>Quite A Bit</i>	<i>Extremely</i>
36. Trouble concentrating	36	0	1	2	3	4
37. Feeling weak in parts of your body	37	0	1	2	3	4
38. Feeling tense or keyed up	38	0	1	2	3	4
39. Thoughts of death or dying	39	0	1	2	3	4
40. Having urges to beat, injure or harm someone	40	0	1	2	3	4
41. Having urges to break or smash things	41	0	1	2	3	4
42. Feeling very self-conscious with others	42	0	1	2	3	4
43. Feeling uneasy in crowds	43	0	1	2	3	4
44. Never feeling close to another person	44	0	1	2	3	4
45. Spells of terror or panic	45	0	1	2	3	4
46. Getting into frequent arguments	46	0	1	2	3	4
47. Feeling nervous when you are left alone	47	0	1	2	3	4
48. Others not giving you proper credit for your achievements	48	0	1	2	3	4
49. Feeling so restless you couldn't sit still	49	0	1	2	3	4
50. Feelings of worthlessness	50	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	51	0	1	2	3	4
52. Feelings of guilt	52	0	1	2	3	4
53. The idea that something is wrong with your mind	53	0	1	2	3	4

Michigan Breast Reconstruction Outcome Study, DAMD17-94-J-4044,

ATTACHMENT B

MBROS UPDATE

The MBROS Update

The Michigan Breast Reconstruction Outcome Study, University of Michigan

Issue 1

March, 1997

2130 Taubman Center
1500 East Medical Center Drive
Ann Arbor, MI 48109-3040
(313) 936-7321

Letter from the Editor

We have started the MBROS Update to keep our enrollees informed of the progress of the study. Preliminary data from the study has recently been presented at a national meeting of plastic surgeons, the Plastic Surgery Research Council. The success of the study is directly related to the time and effort of you, the study participant. We wish to express our great appreciation for your efforts and hope that you will continue your enthusiastic participation until the end of the study.

Edwin G. Wilkins, M.D.

Final Photos to be Requested

Patients who are near completion of their two year study enrollment period will be contacted by their plastic surgeon to take the final study photos. These photos are very important for the assessment of the aesthetic results of reconstruction. Please remember that your identity will be kept strictly confidential and the photos will be identified by study ID only. Your help in getting the photos taken is greatly appreciated.

Reminder - Visit Logs

Your physician visit logs provide us with valuable information about complications from surgery, additional surgical procedures and number of physician visits in general. We appreciate the time you take to complete and return the logs. Keep up the good work!

Enrollment News

Study enrollment has reached 298 active patients. Since inception of the study in August, 1992, we have enrolled 338 patients. Forty of these patients have been withdrawn leaving the current active population of 298. Our enrollment goal of 425 active patients must be achieved by the September 1, 1997.

Following are some demographic data on active patients:

PROCEDURE TYPE

- | | |
|-----------------------|-----|
| • Free TRAM | 86 |
| • Pedicle TRAM | 123 |
| • Implant | 72 |
| • Latissimus Dorsi | 9 |
| • Double Pedicle TRAM | 4 |
| • Other | 4 |

AGE OF PATIENTS

- | | |
|---------------|-----|
| • 65 and over | 17 |
| • 55 to 64 | 59 |
| • 45 to 54 | 113 |
| • 35 to 44 | 76 |
| • 25 to 34 | 16 |
| • Unknown | 17 |

WHERE OUR ENROLLEES LIVE

- | | |
|-------------------|-----|
| • Michigan | 207 |
| • Ontario, Canada | 66 |
| • Louisiana | 10 |
| • Pennsylvania | 2 |
| • Ohio | 3 |
| • Other/Unknown | 10 |

Patients Report no Change in Physical Function after Reconstruction

In a preliminary analysis of the self-reported questionnaire data, we found that patients did not report any significant change in physical function after reconstruction. This is reassuring news, given that both implant and TRAM breast reconstruction may involve the re-positioning of shoulder or abdominal muscles. Overall, the 56 patients included in the analysis indicated that they are not limited in performing the physical activities required in their day to day living due to their reconstructive procedure. The analysis included pre-operative and one year post-operative data.

Let Us Know

Several of you have written us letters or comments regarding your reconstruction, recovery, and fight against breast cancer. We believe that your stories may benefit others in your situation. Therefore, we are planning to include a personal comments and letters section in future newsletters. If you would like to share your thoughts or story with us, please write us at the address listed above. Your story will remain anonymous unless otherwise requested.

Future issues will include a recommended reading section, so if you know of any good books or articles related to reconstruction, cancer, or survivors, please let us know. Your questions about the study or other breast reconstruction issues are also welcomed. We hope to hear from you soon.

The MBROS Update

The Michigan Breast Reconstruction Outcome Study, University of Michigan

Issue 2

June, 1997

2130 Taubman Center
1500 East Medical Center Drive
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(313) 936-7321

Letter from the Editor

It has come to my attention that some of you have questions about the basic study design and goals of the Michigan Breast Reconstruction Outcome Study (MBROS). Therefore, my letter this month provides you with a broad overview of the study. First let me note that, without your generous participation, there would not be a study and we deeply appreciate the time you have donated to this important research project.

MBROS was funded by the Department of Defense Breast Cancer Research Initiative in June, 1994. The goals of MBROS are to examine the long-term results of post-mastectomy breast reconstruction and to compare the outcomes of implant and natural tissue reconstructions. Emphasizing the patient's perspective, this project is examining how breast reconstruction performs in "real life" when used by dozens of surgeons in a diverse population of patients.

Involving 14 medical centers and 24 plastic surgeons in the U.S. and Canada, MBROS has recruited 370 post-mastectomy breast reconstruction patients (towards a goal of 450). During the four year study, a variety of outcome indicators are being assessed, including complication rates, aesthetics, function, psychosocial results, and costs. Patients are evaluated prior to reconstruction and at annual intervals for two years following their surgery. Research tools being used by the project include questionnaires, physical therapy evaluations, chart reviews and hospital cost analysis.

Continued, Third Column

Emotional Benefits of Exercise in Breast Cancer Survivors

Exercise may improve symptoms of depression and anxiety for breast cancer survivors. In a study at the University of Michigan, researchers found that mild to moderate aerobic exercise significantly decreased depressive and anxiety symptoms among breast cancer survivors.

According to the American Cancer society, one out of every nine women in the United States develops breast cancer at some point in her life. The most common form of treatment for breast cancer, mastectomy, can have a serious impact on women's emotional health and well being. Depression, anxiety and devalued self-worth are frequently reported by breast cancer survivors. According to the recent study, one promising strategy for the treatment of the psychological impact of mastectomy is a therapeutic exercise program. The study *Psychological Health Following Mastectomy: the Role of Physical Activity*, was conducted by a research team that included Michelle Segar, M.S., M.P.H., Victor Katch, Ph.D., Randy Roth, Ph.D., Anne Weinstein Garcia, Ph.D., Toby Portner, M.P.H., Scott Glickman, M.S., Sally Haslanger, Ph.D., and Edwin Wilkins, M.D.

The psychological benefits of exercise have been well documented in other populations - largely male subjects, college students and psychiatric patients. However, this study is one of the first to

Continued on Back

Sapient Health Network - On-line support for Breast Cancer Survivors

The Sapient Health Network, SHN, is an internet based health information service developed for patients with chronic and life threatening illnesses. The network includes a breast cancer site. You can reach the SHN on the internet at <http://www.shn.net>, or call (800) 353-1231 for more information. If you are not connected to the internet at home, try your local library or senior center.

The SHN provides a wide range of services including an online library, articles on the latest research and developments, and an area where patients can communicate directly with others in ongoing discussions. We have signed on to the network and find it very informative.

Letter from the Editor Continued

As health care agencies become more cost-conscious, procedures without demonstrated physical and psychosocial benefits may not be supported by insurance companies. There is a critical need for data which shows the functional, psychological and social benefits of such procedures. These benefits must also be assessed in relation to the costs of reconstruction. In essence, we hope that MBROS will demonstrate the value of breast reconstruction for women recovering from breast cancer.

Edwin G. Wilkins, M.D.

Emotional Benefits Continued

investigate the use of aerobic exercise in improving psychological dimensions in breast cancer survivors. Researchers found that mild to moderate aerobic exercise significantly decreased depressive and anxiety symptoms but did not change self-esteem among breast cancer survivors. They also found that patients who had received exercise recommendations from their physicians exercised significantly more than subjects who received no recommendations. As a result, the researchers suggest that health care professionals should consider recommending mild to moderate exercise for breast cancer survivors.

The group notes that the study may have been limited by the small sample size (24 patients). They further note that changes observed in depressive and anxiety symptoms may have been affected by the social interaction and

camaraderie among the participants or between the participants and the investigators. However their data supports inclusion of exercise in breast cancer recovery programs.

Although this study indicates the benefits of exercise, *you should consult your physician before beginning any exercise program.*

In study follow-up researchers found that women, especially in mid-life, experience many barriers to exercise. To address this finding, Michelle Segar, M.S., M.P.H., has developed a program called *Fitting in Fitness* TM that helps women learn how to make exercise a life-long habit. The program is in the pilot phase in Ann Arbor. Ms. Segar is conducting focus groups and collecting data, and plans to package the program so that it can be made widely available in the future. The *Fitting in Fitness* TM program is designed to make exercise user-friendly for busy women.

If you live in the local Ann Arbor area, and are interested in the program, please contact Michelle at (313) 995-9807. We will keep you informed of the progress of Ms. Segar's study.

The following is a list of several other exercise programs in which you may be interested:

"Better than Before Fitness"
50 minute video, \$49.95 (+\$5.95 S&H)
(800) 488-8354

"Dance as a Healing Art"
33 minute video, \$25.00 (\$5.00 S&H)
(800) 888-5236

"Get Up and Go after Breast Surgery",
60 minute video, \$25.00 (\$5.00 S&H)
Varied Directions, Inc.
(800) 888-5236

"In Touch for Life"
A two-videotape kit, free
Zeneca Pharmaceuticals
(800) 842-9920

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MBROS
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The MBROS Update

The Michigan Breast Reconstruction Outcome Study, University of Michigan

Issue 3

September, 1997

2130 Taubman Center
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(313) 936-7321

Letter from the Editor

I have just returned from the Annual Symposium of the *World Congress of Surgeons* where I presented preliminary findings of the Michigan Breast Reconstruction Outcome Study. Initial results of the study have been well received throughout the medical community and we have had the opportunity to give fourteen presentations at local, regional and national meetings. Two articles have been submitted for publication and several more are being prepared. We have summarized one of these articles in this newsletter and will keep you informed as we publish study results.

Once again, I would like to thank each of you for the time and effort you have expended to help us with this study. Results from MBROS are providing both patients and physicians with much needed information on the various options for breast reconstruction. Your contributions are extremely important and we appreciate your help.

Edwin G. Wilkins, M.D.

Mammography Screening Suggested for Some TRAM Patients

Mammography is generally not used for detecting cancer recurrence in women who have undergone mastectomy and TRAM flap reconstruction. However, findings from a study at the University of Michigan Medical Center suggest that mammography may indeed be useful in screening for local cancer

Mammography, Continued, Page 2

Reconstruction Enhances Well Being

In a preliminary analysis of 99 patients in the Michigan Breast Reconstruction Outcome Study (MBROS), researchers¹ found that breast reconstruction improves feelings of well-being after mastectomy. The analysis compared the pre-operative questionnaire data with the same data one year after reconstruction. Measurable gains were found in the areas of physical, social and emotional functioning, as well as general mental health and vitality.

The analysis included patients who had implant (25), pedicle TRAM (36) and free TRAM (38) reconstruction. Sixty-eight patients underwent immediate reconstruction and 31 delayed reconstructions. The mean age of patients was 48.8 years. All patients undergoing breast reconstruction noted statistically significant gains in social functioning, general mental health, emotional well-being and vitality postoperatively, as compared to their preoperative status. Social functioning includes the extent to which physical health or emotional problems interfere with normal social activities with family, friends, neighbors and groups. General mental health was assessed by answers to questions about nervousness, depression, feeling calm and peaceful, feeling blue, and feeling happy. Emotional well-being was assessed by answers to questions about feeling sad, coping with the illness, hopefulness, nervousness, worry about dying and worry about getting sicker. The questions about vitality assessed the extent to which

patients felt energetic or tired. From these results we can conclude that one year after reconstruction patients have resumed their normal social activities, are generally happy, and are hopeful about the future.

All patients also reported fewer role limitations. Role limitations include cutting down on the amount of time spent on work or other activities, accomplishing less than you would like, being limited in the kind of work or activities you do or having difficulty performing work or other activities. Role limitations can be caused by either physical health or emotional problems. This finding may be due to the fact that preoperatively, patients who have just been diagnosed with cancer are likely to be limited in their activities and accomplishments due to their preoccupation with dealing with their cancer and its treatment. One-year after surgery they have returned to a much more normal schedule.

As might be expected, patients in the TRAM flap group noted greater abdominal pain and tightness as compared to implant patients. This finding is expected due to the abdominal surgery required for the TRAM procedure, which is not required for implant patients. In contrast, the implant patients reported increased breast pain one year post-operatively compared to TRAM patients. It is possible that this finding is due to the pain associated with tissue expansion post-operatively. Despite these findings, no statistically significant differences in health perceptions,

continued, next column

Well being, continued, Page 2

Well-Being

Continued from page one
 physical functioning, or overall bodily pain were identified between the two groups one year post-operatively, as compared to their preoperative status. Therefore, although both groups report some pain, it does not appear that the pain is so severe that it interferes with normal work or social interactions, or with activities of daily living such as participating in sports, lifting, running or walking, cleaning, etc.

A number of significant differences were identified between patients undergoing immediate and delayed breast reconstruction. Preoperatively, patients undergoing delayed reconstruction were less satisfied with clothing fit, "feelings of being whole", and general health perception as compared to immediate reconstruction patients. This finding may be due to the fact that delayed reconstruction patients have lived for some time without a reconstructed breast and were dissatisfied with their situation. Patients in the delayed reconstruction group also noted a significantly better emotional status prior to surgery than those in the immediate reconstruction group. This finding is probably due to the fact that patients in the immediate

continued, next column

reconstruction group have just been diagnosed with cancer and are going through a great deal of emotional turmoil as a result of their disease. Patients in the delayed reconstruction group have had time to deal with their illness and usually finish all cancer treatment prior to their reconstruction. As might be expected, patients in the delayed reconstruction group had greater increases in their satisfaction with the fit of their clothing and feelings of being whole one year after surgery as compared to those in the immediate reconstruction group.

Overall, it appears that breast reconstruction makes patients feel better and that there are no significant detrimental effects on general health status, overall bodily pain or physical functioning as a result of reconstructive surgery.

I- PS Cederna, EG Wilkins, JC Lowery, SL Goldfarb, A Perkins.

Mammography

Continued from Page one

recurrence in patients initially treated for extensive ductal carcinoma in situ (DCIS) with simple mastectomy and immediate TRAM reconstruction. It should be noted that the study's findings do not suggest that *all* patients who have undergone breast reconstruction should have mammograms. The

continued, next column

findings apply only to TRAM patients who have had extensive DCIS and simple mastectomy. The use of mammography for other types of breast reconstruction patients is still under study.

In this study, the researchers analyzed the cases of four patients who had local recurrence of cancer in TRAM flaps. All patients were initially treated for DCIS with simple mastectomy and immediate reconstruction. The local recurrences occurred within an average period of three years after mastectomy. Three of the four recurrences were detected by physical exam and the remaining local recurrence was found by screening mammography.

While the researchers noted that the local recurrence of cancer in reconstructed breasts is relatively rare, they concluded that all patients undergoing mastectomy and TRAM reconstruction for extensive DCIS should undergo annual mammography postoperatively for at least five years from the time of the mastectomy. However, physical examination remains the best way to detect local recurrence of cancer. Women who have undergone mastectomy and reconstruction should continue to perform monthly self exams of their breasts and receive periodic physical exams as recommended by their health care providers.